

REMARKS

Claims 54-59, 61-65, 67, 69-85, 87-92, 95 and 97-102 and 106-108 are pending. Claims 1-53, 60 68, 86, and 96 were previously canceled and claims 66, 93-94, and 103-105 are cancelled herein without prejudice or disclaimer to the subject matter to which they pertain. Claims 85, 90, 95 and 107 are amended. Applicants retain the right to file continuing applications. New claims 108-113 has been added. No new matter has been added.

Applicants gratefully acknowledge that claims 54-59, 61-65, 67, 69-84 and 107 are allowable.

Applicant respectfully submits that entry of the above claim amendments is proper under 37 C.F.R. § 1.116 because the amendments: (a) place the application in condition for allowance (for the reasons discussed herein); (b) do not raise any new issues requiring further search and/or consideration (since the amendments amplify issues previously discussed throughout the prosecution), except to the extent that searches for up to additional 10 variant sequences within this application is reasonable pursuant to 37 C.F.R. §1.141 and MPEP 803.04; (c) do not present any additional claims requiring further examination; and (d) place the application in better form for appeal. Thus, entry of the foregoing amendments, reconsideration and reexamination of the claimed subject matter are respectfully requested.

Formalities

The language of claims 85, 95 and 107 have been amended to be consistent with amendments made in response to the September 30, 2004 office action. In particular, the phrase “regulatory element” has been changed to “enhancer element”.

Claim Objections

Claims 66, 103 and 105 are objected to under 37 CFR 1.75(c) as allegedly being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicants respectfully submit that the objection is obviated in view of the herein claimed invention. In particular, claim 66, 103 and 105 have been cancelled. Accordingly, Applicants respectfully request reconsideration and withdrawal of the objections.

Rejection Under 35 U.S.C. §112, first paragraph

Claims 85, 87-95, 97-105 are rejected under 35 U.S.C. §112, first paragraph (enablement), because while being enabled for (i) *in vitro* embodiments directed to expression of a desired polypeptide sequence when the polynucleotide sequence is operatively linked to the recited PSMA enhancer element and promoter, and (ii) methods of treating prostate cancer wherein the vector used comprises a recombinant expression cassette comprising a polynucleotide sequence encoding an enzyme that converts a prodrug to a toxic drug operatively linked to both an enhancer element obtained from intron 3 of the PSM gene and a promoter element, these claims are allegedly not enabled any other *in vivo* embodiments wherein the claimed regulatory elements are used to direct expression of a given heterologous sequence. Applicants traverse this rejection for reasons of record and to the extent it applies to the herein claimed invention.

The claimed invention is enabled because the specification teaches those skilled in the art how to make and use the full scope of the claimed invention directed to a novel regulatory element derived from a prostate specific gene for expression of genes in prostate cells to treat prostate cancer, without undue experimentation. All that is necessary is that one skilled in the art be able to practice the claimed invention, given the level of knowledge and skill in the art. *In re*

Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Applicants disclose methods of directing expression of a coding sequence in prostate and methods of treating prostate cancer comprising, administering an expression cassette comprising an enhancer element obtained from intron 3 of the PSM gene, a promoter and a coding sequence, wherein the enhancer and promoter direct expression of the coding sequence. It is not necessary to disclose everything necessary to practice the invention, and it is best to omit the well-known. *In re Buchner*, 929 F.2d, 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991). It is well known to those of skill in the art which coding sequences are expressed in prostate cells and/or used to treat prostate cancer.

Enclosed are exemplary abstracts showing a few of the many genes used to treat prostate cancer. See e.g., Uchida A., et al. In vivo suicide gene therapy model using a newly discovered prostate-specific membrane antigen promoter/enhancer: a potential alternative approach to androgen deprivation therapy. *Urology*. 2001 Aug;58(2 Suppl 1):132-9 that discloses expression of a suicide gene, cytosine deaminase (CD) in vivo as a treatment for prostate cancer; Ikegami, S. et al., Treatment efficiency of a suicide gene therapy using prostate-specific membrane antigen promoter/enhancer in a castrated mouse model of prostate cancer. *Cancer Sci.* 2004 Apr;95(4):367-70 that discloses expression of another suicide gene, herpes virus thymidine in prostate cancer cells; Cheng, W.S., et al., A novel TARP-promoter-based adenovirus against hormone-dependent and hormone-refractory prostate cancer. *Mol Ther.* 2004 Aug;10(2):355-64 that discloses adenovirus expression for the treatment of prostate cancer; and Lee S.J., et al., Targeting prostate cancer with conditionally replicative adenovirus using PSMA enhancer. *Mol Ther.* 2004 Dec;10(6):1051-8 discloses viral E1a protein expression in prostate. Accordingly, the Applicants respectfully request reconsideration and withdrawal of the rejection.

In addition, new claims 108-113 have been added to depend from claims 85 or 95 to expressly claim a coding sequence that encodes a toxin, a protein involved in viral replication, or an enzyme which converts a prodrug to a toxic drug. Support for scope of the new claims is found on at least page 7, paragraph 10 and Figure 12, as described on the last paragraph on page 12 continuing on to page 13. Applicants therefore respectfully submit that such new claims are not new matter requiring further examination, and request consideration and entry of these claims after final rejection.

CONCLUSION

Early consideration, entry of the Amendment and Reply After Final, favorable consideration and prompt allowance of the pending claims are respectfully believed to be in order and respectfully requested. **If anything else is necessary to place this application in condition for allowance, e.g., by Examiner's Amendment, Applicant respectfully requests that the Examiner contact the undersigned representative at the telephone number listed below.**

**To the extent necessary, please grant any extension of time deemed necessary for
entry of this communication. Please charge any deficient fees, or credit any overpayment
of fees, to Deposit Account 500417.**

Respectfully submitted,

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